



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 5, 2018

David Chi
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –

- Remove Western bean cutworm (*R. albicosta*) as a target pest;
- Replace “524-AGR” with “524-631;”
- Modify designations for the active and inactive ingredients;
- Replace “RIB Complete®” with “Seed Blend” in Primary Brand Name;
- Remove SmartStax® Pro RIB Complete® corn blend as an Alternate Brand Name;
- Make minor changes to the Directions for Use.

Product Name: MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend
EPA Registration Number: 524-631
Application Date: 3/29/2018
OPP Decision Number: 542193

Dear Mr. Chi:

In an application dated March 29, 2018, you notified the U.S. Environmental Protection Agency (EPA) that you requested to remove Western bean cutworm (*R. albicosta*) as a target pest, replace “524-AGR” with “524-631”, modify designations for the active and inactive ingredients, replace “RIB Complete®” with “Seed Blend” in Primary Brand Name, remove SmartStax® Pro RIB Complete® as an Alternate Brand Name, and make minor changes to the Directions for Use from your label. Subsequently, the EPA determined that the actions requested do not fall under the scope of Pesticide Registration Notice 98-10 and therefore converted the notification to a non-PRIA amendment (OPP Decision No. 542193). The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

The primary brand name of this product has been changed from MON 89034 x TC1507 x MON 87411 x DAS-59122-7 RIB Complete® to MON 89034 x TC1507 x MON 87411 x DAS-59122-7 Seed Blend. Additionally, the alternate brand name SmartStax®PRO RIB Complete® corn has been removed from the registration. Our records have been updated accordingly. This approval does not affect any terms or

conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Matt Weiner by phone at 703-347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a stylized, flowing script.

Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Plant-Incorporated Protectant Label

MON 89034 × TC1507 × MON 87411 × DAS-59122-7 Seed Blend

Insect-Protected, Herbicide-Tolerant Corn

(OECD Unique Identifier: MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7)

Active Ingredients:

dsRNA transcript comprising a DvSnf7 inverted repeat sequence derived from *Diabrotica virgifera virgifera*, and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7) ≤ 0.00000044%*

Bacillus thuringiensis Cry1A.105 protein and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7) ≤ 0.0088%*

Bacillus thuringiensis Cry2Ab2 protein and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7) ≤ 0.0048%*

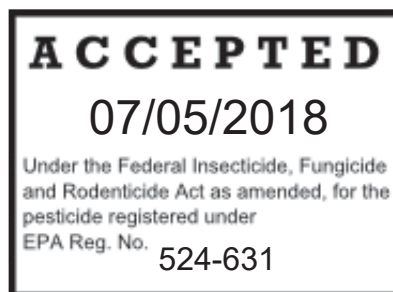
Bacillus thuringiensis Cry1F protein and the genetic material (vector PHP8999) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7) ≤ 0.00096%*

Bacillus thuringiensis Cry3Bb1 protein and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS 59122 7) ≤ 0.0041%*

Bacillus thuringiensis Cry34Ab1 protein and the genetic material (vector PHP17662) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7) ≤ 0.012%*

Bacillus thuringiensis Cry35Ab1 protein and the genetic material (vector PHP17662) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7) ≤ 0.0026%*

Other Ingredients:



The marker protein CP4 EPSPS and the genetic material (vector PV-ZMIR10871) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7) ≤ 0.036%*

The marker protein PAT and the genetic material (vector PHP17662) necessary for its production in MON 89034 × TC1507 × MON 87411 × DAS-59122-7 (OECD Unique Identifier MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7) ≤ 0.0001%*

*Percentage (wt/wt) on a dry weight basis for forage tissue

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS _____

EPA Registration No. 524-631

EPA Establishment No. 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product must be used as specified in the terms and conditions of the registration.

This Plant-Incorporated Protectant (PIP) may be combined or produced through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend protects corn crops from leaf, stalk, and ear damage caused by lepidopteran corn pests listed on this label and root damage caused by corn rootworm larvae listed on this label. In order to minimize the risk of these pests developing resistance to MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend, an insect resistance management plan must be implemented as defined in the registration terms and conditions.

Grower agreements will specify that growers must adhere to the refuge requirements that will be described on the bag or bag/tag for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend or other applicable product use documents.

Sales of corn hybrids that contain Monsanto's *Bt* corn plant-incorporated pesticide(s) must be accompanied by either an IRM/Grower Guide or information on the bag or bag-tag on planting, production, and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *B.t.* proteins is planted.

Corn seed bags or bag tags for products containing MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend must include the refuge size requirement in text and graphical format.

INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management in the bag and/or bag-tag.

For the sole purpose of manufacturing and small scale research trials for observation, these refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

The seed producer must ensure a minimum of 5% non-PIP refuge seed is included with MON 89034 × TC1507 × MON 87411 × DAS-59122-7 in each lot of seed corn. The refuge seed in the seed mixture may not be treated with seed-applied insecticides for corn rootworm (CRW) control unless the MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed in the seed mixture receives the same treatment.

The IRM/Grower Guide for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend or comparable information presented on the product bag or bag-tag must contain the following information:

This product is a seed mixture containing MON 89034 × TC1507 × MON 87411 × DAS-59122-7 and a minimum of 5% non-*B.t.* seed that when planted creates an interspersed refuge within the field. There are no requirements for a separate structured refuge for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend when planted in the U.S. corn-growing region, including Alaska and Hawaii, because the refuge seed is contained within the bag/container.

The interspersed refuge can only be used by planting seed corn specifically generated by qualified seed producers/conditioners licensed by the registrant. Insecticidal treatments labeled for adult CRW control are discouraged during the time of adult CRW emergence.

The seed mix refuge option for MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend satisfies the refuge requirements in all regions other than in the cotton-growing region where corn earworm is a significant pest as defined below.

Additional refuge requirements in the cotton-growing region where corn earworm is a significant pest

In the cotton-growing region where corn earworm is a significant pest, as defined below, MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend requires the planting of an additional 20% structured refuge (i.e., 20 acres of non-*B.t.* corn for every 80 acres of MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend planted).

The 20% refuge must be planted with corn hybrids that do not contain *B.t.* technologies for the control of corn rootworms or corn borers. The refuge and the MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend should be sown on the same day or with the shortest window possible between planting dates to ensure that corn root development is similar among varieties. The structured refuge may be planted as an in-field or adjacent (e.g., across the road) refuge or planted as a separate block that is within ½ mile of the MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend field. In-field refuge options include blocks, perimeter strips (i.e., strips around the field), or in-field strips. If perimeter or in-field strips are implemented, the strips must be at least four (4) consecutive rows wide. The refuge can be protected from lepidopteran damage by use of non-*B.t.* insecticides if the population of one or more target lepidopteran pests of MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend in the refuge exceeds economic thresholds. In addition, the refuge can be protected from CRW damage by an appropriate seed treatment or soil insecticide; however, insecticides labeled for adult CRW control must be avoided in the refuge during the period of CRW adult emergence. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants).

The cotton-growing region requiring the additional 20% refuge consists of the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

Corn Insects Controlled or Suppressed

European corn borer (ECB)	<i>Ostrinia nubilalis</i>
Southwestern corn borer (SWCB)	<i>Diatraea grandiosella</i>
Southern cornstalk borer (SCSB)	<i>Diatraea crambidoides</i>
Corn earworm (CEW)	<i>Helicoverpa zea</i>
Fall armyworm (FAW)	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Lesser corn stalk borer	<i>Elasmopalpus lignosellus</i>
Sugarcane borer (SCB)	<i>Diatraea saccharalis</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western corn rootworm (WCRW)	<i>Diabrotica virgifera virgifera</i>
Northern corn rootworm (NCRW)	<i>Diabrotica barberi</i>
Mexican corn rootworm (MCRW)	<i>Diabrotica virgifera zeae</i>

MON 89034 × TC1507 × MON 87411 × DAS-59122-7 seed blend is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents that can be found at <http://www.monsantotechnology.com>